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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/224,556	12/30/98	DIXIT V	203442102502

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EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1644	7

DATE MAILED: 06/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/224,556	Dixit
Examiner	**Group Art Unit**
Robert C. Hayes	1644

☑ Responsive to communication(s) filed on 12/30/98.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1 and 34-47* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1 and 34-47* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 23-49 have been renumbered 22-47.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 & 34, drawn to a purified CD40 mammalian protein, classified in Class 530, subclasses 350.

II. Claims 35-38, 43 & 47, drawn to an isolated nucleic acid molecule, compositions of such not involving gene therapy, expression vectors, host cells, a method of producing a CD40 binding protein, classified in Class 435, subclass 69.1.

III. Claim 39-40 & 42, drawn to antibodies and hybridoma cell lines, classified in Class 435, subclass 240.27.

IV. Claim 41, drawn to antagonists to the CD40 receptor, Class/subclass varies.

V. Claim 44, drawn to a method of modulating cellular function by transfecting cells with nucleic acids encoding CD40 binding proteins, classified in Class 435, subclass 6.

VI. Claim 45-46, drawn to a method for screening for a CD40 immunosuppressive agent, classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-IV are directed to products that are physically and functionally distinct, which include protein, nucleic acid, antibodies and antagonists. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the binding protein of Group I is a fundamentally different molecule than the nucleic acid molecule of Group II, which in turn can be used to clone the protein, detect expression of the protein, or used as therapeutic agents in gene therapy. The protein of Group I is a fundamentally different molecule than the antibody of Group III, which can be generated by immunizing animals with a small synthetic portion of the full length polypeptide. Although the antibody of Group III can be used in isolating the protein of Group I,

the antibody can also be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as a therapeutic agents themselves. Moreover, the proteins of Group II can be utilized in making the antibodies of Group III, but not vice versa. Although the antagonists of Group IV can be proteins or antibodies, any agent that blocks the activity of the proteins of Group I is an antagonist, including chemical compounds that have no structural relationship to the nucleic acids of Group II, proteins of Group I or antibodies of Group III, and vice versa. Additionally, neither the proteins of Group I, antibodies of Group III or antagonists of Group IV require the vectors and host cells of Group II, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Although there are provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups V-VI are directed to methods to modulate cellular functions or to screen immunosuppressive agents for CD40 binding protein. Each of the methods require physically and functionally distinct elements and possess limitations with different and distinct goals. For example, the use of transfected cells in Group V to express the CD40 binding protein or an anti-CD40 antibody are distinct from the use of the CD40 receptor protein to detect immuno-suppressive agents as in Group VI. Additionally, the method of Group V requiring a cellular

function assay does not require the CD40 receptor bound to a solid support, as required in Group VI, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Inventions I, III-IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the binding protein of Group I, the antibodies of Group III and the antagonists of Group IV can be used in other diagnostic or therapeutic methods, such as isolating related proteins by affinity chromatography, or used to detect problems with immunoglobulin expression, or used in any of the distinct inventions of Groups I, III & IV as stated above. In contrast, the method of screening agents of Group VI requires constructs expressing various nucleic acids, which are not required for the products of Groups I, III or IV, and vice versa.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown as stated above (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of Group II can be used to encode the full length protein or antibody, detect expression of the protein or antibody, or used in gene therapy. In contrast, the method of modulating cellular function in Group V requires an assay to determine such, which is not required for the products of Group II, and vice versa.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternative Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
May 31, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640